UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE NEW YORK TIMES COMPANY, DANIELLE IVORY, and NATASHA SINGER,	:	
Plaintiffs,	:	**COMPLAINT**
- against -	:	19-cv-5640
FOOD AND DRUG ADMINISTRATION,	:	
Defendant.	:	

Plaintiffs THE NEW YORK TIMES COMPANY, DANIELLE IVORY, and NATASHA SINGER, by their undersigned attorneys, allege for their Complaint:

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), to obtain an order for the production of agency records from the Food and Drug Administration ("FDA") in response to a request properly made by Plaintiffs (together, "The Times").

PARTIES

2. Plaintiff The New York Times Company publishes *The New York Times* newspaper and www.nytimes.com. The New York Times Company is headquartered in this judicial district at 620 Eighth Avenue, New York, New York.

3. Plaintiff Danielle Ivory is a reporter for *The New York Times* newspaper and an employee of The New York Times Company.

4. Plaintiff Natasha Singer is a reporter for *The New York Times* newspaper and an employee of The New York Times Company.

5. Defendant FDA is an agency of the federal government that has possession and control of the records that Plaintiffs seek.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

7. Venue is premised on the place of business of Plaintiffs and is proper in this district under 5 U.S.C. § 552(a)(4)(B).

8. Plaintiffs have exhausted all administrative remedies available in regard to the request at issue. See U.S.C. § 552(a)(6)(C).

FACTS

9. On December 20, 2018, Plaintiff Danielle Ivory submitted a FOIA request on behalf of herself and Plaintiff Natasha Singer to the FDA for documents related to the FDA's Digital Health Software Precertification Program (the "Request"). This Request seeks "copies of (or access to) documents pertaining to the Digital Health Software Precertification (Pre-Cert) Program," in particular "[a]ll email correspondence between Jan. 1, 2017, and the present, that includes Bakul Patel and Linda Ricci at the FDA" and parties with email addresses containing certain domain names, and containing particular keywords or variants of those words. *See* Exhibit A.

10. Pursuant to 5 U.S.C. § 552(a)(6)(E), The Times also sought expedited processing of the request. *See id.*

11. On December 20, 2018, the FDA acknowledged receipt of the Request, assigning the Request reference number FDA1849549. The FDA subsequently assigned the Request control number 2019-285.

12. On January 30, 2019, the FDA denied The Times's request for expedited processing.

13. Between April and June 2019, representatives for The Times communicated with the Director of the Division of Information Disclosure at the FDA's Center for Devices and Radiological Health in an effort to expedite the Request. In April, the Director informed a representative of The Times that the agency "expect[s] the request to be completed by January 2021." Subsequently, the Director informed counsel for The Times that it could not expedite the Request but would "continue to try our best and process the request as soon as possible."

14. The Times has received no further communications from the FDA regarding the Request.

COUNT I

15. Plaintiffs repeat, reallege, and reincorporate the allegations in the foregoing paragraphs as though fully set forth herein.

16. The FDA is an agency subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any other materials as to which it is claiming an exemption.

17. Plaintiffs have exhausted all administrative remedies under FOIA as to the Request, because the FDA failed to make a determination in regard to the Request within 20 business days. *See* 5 U.S.C. § 552(a)(6)(A), (C).

18. Accordingly, Plaintiffs are entitled to an order compelling the FDA to produce records responsive to the Request.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

19. Declare that the documents sought by the Request, as described in the foregoing paragraphs, are public under 5 U.S.C. § 552 and must be disclosed;

20. Order the FDA to undertake an adequate search for the requested records and provide those records to Plaintiffs within 20 business days of the Court's order;

21. Award Plaintiffs the costs of this proceeding, including reasonable attorney's fees, as expressly permitted by FOIA; and

22. Grant Plaintiffs such other and further relief as this Court deems just and proper.

Dated: New York, New York
June 17, 2019

/s/

David E. McCraw, Esq.
Dana R. Green, Esq.
Legal Department
The New York Times Company
620 8th Avenue
New York, NY 10018
Phone: (212) 556-4031
Fax: (212) 556-4634
E-mail: mccraw@nytimes.com

Counsel for Plaintiffs